# **Amendments to the Drawings**

Original Figures 1-9 are being replaced herewith with more legible and reproducible copies. Replacements sheets 1-9 are attached to this response.

### REMARKS

Claims 1 has been amended to delete specific moieties from the group of moieties for R1 and R2 and to delete reference to dideaza and deaza analogues. Claims dependent on claim 1 have been amended to delete subject matter no longer within the scope of amended claim 1. Claims 23-31 and 33-60 have been cancelled without prejudice to pursuing such claims in a continuing or divisional application. New dependent claims 67-79 have been added. Many of the claims have been amended so ensure that R1 through R5 are consistent and to present the moieties in such groups in the alternative. With the foregoing amendments claims 1, 2, 4-22 and 67-79 are pending in the application.

# **Drawings**

A revised set of drawings is submitted herewith. No new matter has been introduced with the revised drawings and therefore there is no need to submit annotated marked sheets, and only "Replacements" sheets accompany this response..

#### Information Disclosure Statement

A supplemental Information Disclosure Statement is submitted herewith that provides full references to the previously submitted abstracts to the extent such references are available to Applicant's attorney.

# Rejection under 35 USC § 112, first paragraph (Written Description)

The claims were rejected on the ground that the specification does not describe the claimed subject matter in such a way as to convey that the inventors were in possession of the claimed invention at the time the application was filed.

The Applicant does not agree with this characterization. Table 1 discloses a plethora of compounds made and tested by the inventors for there affect on PKAI, PKAII and Epac. See Table 2.

The Federal Circuit in *Carnegie Mellon University v. Hoffman-LaRoche, Inc.*, 541 F.3d 1115 (Fed. Cir. 2008) discussed the case law on the written description requirement. The Court also stated:

The Guidelines for Examination of Patent Applications under the 35 U.S.C. § 112, ¶ 1, "Written Description" Requirement, 66 Fed. Reg. 10-99 (Jan. 5, 2001) ("Guidelines"), which we find to be an accurate description of the law by the agency responsible for examining patent applications, and thus persuasive authority, provide further guidance for determining whether the written description requirement is met for claims drawn to a genus. The Guidelines state:

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species ... by disclosure of relevant, identifying characteristics, *i.e.*, structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus.

A "representative number of species" means that the *species which are* adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

\* \* \*

Satisfactory disclosure of a "representative number" depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed. For inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus.

Guidelines, 66 Fed. Reg. at 1106 (emphases added).

Carnegie Mellon, 541 F.3d at 1125.

The disclosure of so many species within the scope of originally filed claim 1 clearly indicates that the specification fully complies with the written description requirement by disclosing a representative number of species within the claimed genus. Given that the scope of claim 1 has been substantially narrowed by the amendment made herein, it and the remainder of the claims necessarily are sufficiently described in the specification to satisfy the written description requirement.

Rejection under 35 USC § 112, first paragraph (Enablement)

The examiner has rejected the claims as being not enabled because the vast array of compounds, pharmaceutical compositions and methods of disease treatment encompassed by the claims would require undue experimentation to practice the invention.

The Wands factors were discussed by the examiner under the written description rejection. In that section the examiner asserted that (1) the disclosure could not be extrapolated to compounds that included dideaza and deaza analogues, selenium containing substituents and the generic substituent "silyl" and (2) the administration of silyl- or selenium-substituted cAMP for the treatment of any disease condition has not been disclosed.

Dideaza and deaza analogues, selenium containing substituents and the generic substituent "silyl" have been deleted from the claims and the method of treatment claims have been cancelled, each without prejudice to further prosecution by the applicant.

Based on these amendments it is submitted that the presently pending claims are fully enabled.

# Rejection under 35 USC § 112, second paragraph

The claims are rejected as indefinite. Applicant has amended the claims so that the various substituents are presented in the alternative.

In addition, applicant has amended claim 1 to delete reference to "esters". Applicant has note deleted reference to "solvates" as the skilled artisan would know that compounds within the scope of claim 1 could form solvates depending on which solvent the compound was exposed to.

Claim 1 has been amended to add the proviso language suggested by the examiner.

The term "azido" as set forth under **R1** in claim 1 has not been deleted. It is submitted that this substituent is within the scope of the elected subject mater. The various other substituents of **R1** cover a wide variety of chemical moieties. Why "azido" is singled out as not being within the scope of the elected subject matter while the others are within such scope is unclear to applicant.

# Rejection under 35 USC § 102

Claims 1, 2, 4-22, 29, 30, 33, 35, 37-55 and 62-66 are rejected as being anticipated by Kataoka et al. '792 as explained by English abstract C2. This reference discloses hydrogen, lower alkylamino, lower alkylthio, arylalkylthio and halo at the position corresponding to **R1** in claim 1. This subject matter has been cancelled from claim 1. However, 2-hydroxyethylthio and 2-aminoethylthio have been added to replace S-alkyl. Support for this amendment can be found in Claim 3. Based on this amendment, the claims are novel over Kataoka et al. '792.

Claims 1, 2, 4-15, 29, 30, and 32 are rejected as being anticipated by Weimann et al. '885. The abstract in Weimann discloses a compound where Y is hydroxyl when X is hydrogen, and Z is hydrogen, an ether group or a mono- or disubstituted amine or when X is other than hydrogen, Y is hydrogen. Y corresponds to **R1** in claim 1. **R1** has been amended to delete hydrogen and –OH. As amended, the claims are novel over Weimann et al.

Claims 1, 2, 4-15, 29, 30, and 32 are rejected as being anticipated by Sopchik et al. The compound labeled "cis-13" and "cis-14" have hydrogen at the position corresponding to **R2** in claim 1. Claim 1 has been amended to delete hydrogen from **R2**. As amended, the claims are novel over Sopchik et al.

Claims 1, 2, 4-15, 29, 30, and 32 are rejected as being anticipated by Kataoka et al.

Compounds 3a-d all contain hydrogen at the position corresponding to **R1** in claim 1. Claim 1 has been amended to cancel hydrogen from **R1**. As amended the claims are novel over Kataoka et al.

Claims 1, 2, 4-15, 29, 30, and 32 are rejected as being anticipated by Ikehara. Compound 3 in Ikehara has fluorine at the position corresponding to **R2**. Claim 1 has been amended to exclude fluorine from **R2**. As amended, the claims are novel over Ikehara.

Claims 1, 2, 4-15, 29, 30, and 32 are rejected as being anticipated by Gulyeav et al. The structure at page two discloses a tautomer where in its other form has hydroxide at the position corresponding to **R2** in claim 1. Hydroxide has been cancelled from **R2** in claim 1. As amended, the claims are novel over Gulyeav et al.

### Conclusion

Based on the foregoing, the specification provides an adequate written description and enablement for the presently pending claims. Further, the pending claims are patentable over the art of record.

While Applicants believe that no further fees are due at this time, the Commission is authorized to charge any fees that may be due as a result of filing this amendment, including additional claim fees not already paid for, or other fees that have not been separately paid, to Deposit Account 50-0310 (Our Order No.: 067670-5004-US).

Please direct any calls in connection with this application to the undersigned at (415) 442 1255.

> Respectfully submitted, MORGAN LEWIS & BOCKIUS LLP

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